NOV 1 6 2000

K002572

VI. Safety and Effectiveness Summary

This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.87

Establishment Registration Number: 2021898

Address of Manufacturer:

Medtronic PS Medical
125 Cremona Drive
Goleta CA, 93117
(805) 968-1546 ext. 1776
Fax: (805) 968-5617

Contact Person: Janet McAuley

Date: June 26, 2000

Trade or Proprietary Name: Medtronic PS Medical ChannelScope Endoscope,

Common usual or Classification Name: Neurological Endoscope (882.1480)

Predicate Device Identification: Clarus ChannelScope Endoscope (K945633)

Description: The Medtronic PS Medical, ChannelScope Endoscope is a flexible tubular device with a formed plastic proximal handle. The endoscope has a working channel. The working channel allows the passage of surgical instruments or a BiPolar Pencil.

Intended Use: The Medtronic PS Medical ChannelScope neuroendoscopes are indicated for diagnostic and intraopertive procedures where the physician desires direct vision of intracranial tissue where cerebrospinal fluid (CSF) may be contacted. These procedures include third ventriculostomy, tumor biopsy, cyst fenestration or removal, septostomy, septum pellucidotomy, loculated hydrocephalus, colloid cyst removal and for removal of CSF shunt catheters. The Channel neuroendoscopes have a working channel intended for the passage of surgical instruments which are used for accessing the ventricles, tumor removal, shunt placement, and other intracranial procedures. The High Resolution Channel NeuroEndoscope has a working channel of 2.15mm, and an outer diameter of 4.22 mm; it is available in two working lengths, 13.0 cm and 21.6. cm. The Standard Resolution ChannelScopes have a working channel of 2.15 mm and an outer diameter of 3.5 mm in 13.0 cm or 21.6 cm lengths or a working channel of 3.15 mm and an outer diameter of 4.5 mm in 13.0 cm or 21.6 cm lengths.

Intended Use of predicate device: "The ChannelScope neuroendoscopes are indicated for diagnostic and intraoperative procedures where the physician desires direct vision of intracranial tissue where cerebrospinal fluid (CSF) may be contacted. The Channel neuroendoscopes has a working channel intended for the passage of surgical instruments which are used for accessing the ventricles, tumor removal, shunt placement, and other intracranial procedures. The High Resolution Channel NeuroEndoscope has a working channel of 2.15mm and an outer diameter of 4.22 mm; it is available in two working lengths, 13.0 cm and 21.6 cm."

Technological comparison: Medtronic PS Medical submits that the materials of fabrication, intended uses, performance characteristics and design specifications of the ChannelScope Endoscope are substantially equivalent to those of the predicate device. Based upon the summary above, Medtronic PS Medical determines substantial equivalence, safety, and efficacy of the ChannelScope Endoscope based upon the predicate and currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2000

Ms. Janet McAuley
Regulatory Specialist
Medtronic PS Medical
125 Cremona Drive
Goleta, California 93117

Re: K002572
Trade Name: Medtronic PS Medical Channelscope Endoscope
Regulatory Class: II
Product Code: GXG
Dated: August 14, 2000
Received: August 18, 2000

Dear Ms. McAuley:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002572

Device Name: ChannelScope Endoscope Abbreviated 510(k) Number (if known):

Indications for Use:

The Medtronic PS Medical ChannelScope neuroendoscopes are indicated for diagnostic and intraopertive procedures where the physician desires direct vision of intracranial tissue where cerebrospinal fluid (CSF) may be contacted. These procedures include third ventriculostomy, tumor biopsy, cyst fenestration or removal, septostomy, septum pellucidotomy, loculated hydrocephalus, colloid cyst removal and for removal of CSF shunt catheters. The Channel neuroendoscopes have a working channel intended for the passage of surgical instruments which are used for accessing the ventricles, tumor removal, shunt placement, and other intracranial procedures. The High Resolution Channel NeuroEndoscope has a working channel of 2.15mm, and an outer diameter of 4.22 mm; it is available in two working lengths, 13.0 cm and 21.6. cm. The Standard Resolution ChannelScopes have a working channel of 2.15 mm and an outer diameter of 3.5 mm in 13.0 cm or 21.6 cm lengths or a working channel of 3.15 mm and an outer diameter of 4.5 mm in 13.0 cm or 21.6 cm lengths.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Over the Counter Use:
or
Prescription Use: X
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K002572

(optional format 1-2-96)